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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,598	09/18/2001	Vito V. Florio	3470.002A	1662

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DENNIS G. LAPOINTE
LAPOINTE LAW GROUP, PL
PO BOX 1294
TARPON SPRINGS, FL 34688-1294

EXAMINER	
TOMASZEWSKI, MICHAEL	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
05/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/955,598	FLORIO ET AL.	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/27/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the application filed on 9/18/01. Claims 1-15 are pending. The IDS statement filed 11/27/01 has been entered and considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by *Joao* (6,283,761; hereinafter *Joao*).

(A) As per claim 1, *Joao* discloses an Integrative Medicine Health Care Program for prescribing unregulated therapeutic substances as an equivalent or superior treatment option to traditional pharmaceuticals and/or over-the-counter medicines within a mainstream medical care environment comprising:

(1) a mainstream medical care environment comprising a Medical Care Entity staffed by one or more medical professionals having responsibility for treatment of patients with traditional medicines, natural therapeutics, nutritional supplements and combinations thereof, for a given medical condition (*Joao*: col. 2, line 65-col. 3, line 7);

(2) means for identification of an unregulated therapeutic substance as a natural treatment for said given medical condition within said Medical Care Entity (*Joao*: col. 20, lines 9-12);

(3) means for alerting said Medical Care Entity and its one or more medical professionals responsible for overseeing the care of said patients for said given medical condition, of the availability within the Program of said unregulated therapeutic substance as the natural treatment of the given medical condition (*Joao*: col. 5, lines 7-18);

(4) means for soliciting said one or more medical professionals and their patients diagnosed with said given medical condition, to participate in the Program with the initiation of a treatment protocol for said unregulated therapeutic substance (*Joao*: col. 2-line 65-col. 3, line 7);

(5) means for qualifying said patients in said Medical Care Entity for participation in the Program (*Joao*: col. 4, lines 40-47); and

(6) means for administering said unregulated therapeutic substance to said qualified patients in accordance with a natural therapeutic treatment

regimen, under the supervision of said Medical Care Entity (*Joao*: col. 9, lines 39-45);

(7) wherein said unregulated therapeutic substance is obtained by the patient for administering to said patient by a prescription provided by the Medical Care Entity (*Joao*: col. 19, lines 12-21); and

(8) wherein the administering of the unregulated therapeutic substance is administered as part of an integrative medical protocol within the mainstream medical care environment (*Joao*: col. 20, lines 9-12).

(B) As per claim 2, *Joao* discloses the Program according to Claim 1, wherein the administering of the unregulated therapeutic substance is administered as part of the integrative medical protocol within the mainstream medical care environment as an appropriate primary mode of treatment (*Joao*: col. 20, lines 9-12).

(C) As per claim 3, *Joao* discloses the Program according to Claim 1, wherein the administering of the unregulated therapeutic substance is administered as part of the integrative medical protocol within the mainstream medical care environment as an appropriate complimentary and alternative mode of treatment (*Joao*: col. 20, lines 9-12).

(D) As per claim 4, *Joao* discloses the Program according to Claim 1, further comprising: means for monitoring patient response to said unregulated therapeutic substance, within said Medical Care Entity (*Joao*: col. 5, lines 45-50).

(E) As per claim 5, *Joao* discloses the Program according to Claim 1, wherein each qualified patient is empowered to specify said unregulated therapeutic substance as a natural treatment for said qualified patient's given medical condition (*Joao*: col. 4, lines 27-33).

(F) As per claim 6, *Joao* discloses the Program according to Claim 1, further comprising: means for disseminating to the Medical Care Entity and its patients up-to-date technical and product information related to said unregulated therapeutic substance as a natural treatment for said given medical condition (*Joao*: col. 2, line 63-col. 3, line7).

(G) As per claim 7, *Joao* discloses the Program according to Claim 1, further comprising: means for supplying said unregulated therapeutic substance to patients pursuant to the prescription for said unregulated therapeutic substance issued by the Medical Care Entity (*Joao*: col. 20, lines 9-12).

(H) As per claim 8, *Joao* discloses the Program according to Claim 7, wherein the means for supplying said unregulated therapeutic substance to patients pursuant to the prescription for said unregulated therapeutic substance issued by the Medical Care Entity is a Nutraceutical Supplier of the unregulated therapeutic substance (*Joao*: col. 12, line 58-col. 13, line 7).

(I) As per claim 9, *Joao* discloses the Program according to Claim 8, wherein the Nutraceutical Supplier constitutes and is recognized by the Medical Care Entity and in the Program as a sole source designated Brand Name Nutraceutical Supplier from whom the prescription is filled (*Joao*: col. 12, line 58-col. 13, line 7).

(J) As per claim 10, *Joao* discloses the Program according to Claim 8, wherein the Medical Care Entity includes private medical practices, hospitals, established health care providers such as an HMO and PPO, Insurance Company Sponsored Plans, Union Sponsored Plans administered by a professional health care service provider and government agencies (*Joao*: col. 12, line 58-col. 13, line 7).

(K) As per claim 11, *Joao* discloses the Program according to Claim 10, wherein the Nutraceutical Supplier maintains fully documented natural therapeutic records, including certificates of analysis on each unregulated therapeutic substance and completed documentation related to each unregulated therapeutic substance's efficacy and safety (*Joao*: col. 20, lines 9-12).

(L) As per claim 12, *Joao* discloses the Program according to Claim 11, wherein the Nutraceutical Supplier further provides administrative and support services and education and information services to the Medical Care Entity and the established health care providers (*Joao*: col. 4, lines 48-58).

(M) As per claim 13, *Joao* discloses the Program according to Claim 12, wherein the means for identification of the unregulated therapeutic substance as the natural treatment for the given medical condition is by the Medical Care Entity identifying such unregulated therapeutic substance from one of the administrative and support services, the education and information services, and a combination thereof, provided by the Nutraceutical Supplier (*Joao*: col. 20, lines 9-12).

(N) As per claim 14, *Joao* discloses the Program according to Claim 8, wherein the Nutraceutical Supplier alerts the Medical Care Entity of the availability of the unregulated therapeutic substance as the natural treatment of the given medical condition (*Joao*: col. 4, line 66-col. 5, line 7).

(O) As per claim 15, *Joao* discloses the Program according to Claim 13, wherein the Nutraceutical Supplier further supports the Program by providing educational tools, to the Medical Care Entity, the one or more medical professionals responsible for the patients participating in the Program, and to the patients themselves, the educational tools being in the form of an Internet based service that would provide answers to user questions, and in the form of searchable database services, including, technical reference articles, related to the natural therapeutics and nutritional supplements, to alert the one or more medical professionals and patients to contra indications and

potential interactions between the natural treatment for the given medical condition and the prescription for the unregulated therapeutic substance (*Joao*: col. 4, lines 48-58).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches customized food selection, ordering and distribution system and method (US 2002/004749).

The cited but not applied prior art also includes non-patent literature articles by Kramer, Klaus ("Nutraceuticals in Health and Disease Prevention" Copyright 2001.); Wildman, Robert E. C. ("Handbook of Nutraceuticals and Functional Foods" Copyright 2001.); Sloan, A. Elizabeth ("Nutraceuticals: A Storewide Category" Jul 1999. Supermarket Business. Vol. 54, Iss. 7. pp. 106.); and Holleran, Joan. ("Nutraceuticals: Are They Here To Stay" Oct 1998. Beverage Industry. Vol. 89, Iss. 10. pp. 56.).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MT

ALEXANDER KALINOWSKI
SUPERVISORY PATENT EXAMINER